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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,045	10/20/2005	Edwin Douglas Lephart	12957/20	6027

757 7590 04/06/2009

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EXAMINER	
ZAREK, PAUL E	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
04/06/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,045	LEPHART ET AL.	
	Examiner	Art Unit	
	Paul Zarek	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-25, 29-31, 35, 36, and 45-47* is/are pending in the application.

4a) Of the above claim(s) *47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-25, 29-31, 35, 36, 45, and 46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/10/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 23-25, 29-31, 35, and 36 have been amended, Claims 43-47 have been added, and Claims 26-28, 32-34, and 37-44 have been cancelled by the Applicant in correspondence filed on 02/10/2009. Claims 23-25, 29-31, 35, 36, and 45-47 are currently pending. This is the second Office Action on the merits of the claim(s).

Election/Restrictions

2. Newly submitted Claim 47 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 47 is drawn to a pharmaceutical composition, which is patentably distinct from the methods of treatment already examined. Had Claim 47 been a part of the original set of claims, it would have been subject to a restriction requirement.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, Claim 47 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. Claims 23-25, 29-31, 35, 36, 45, and 46 are examined herein.

RESPONSE TO ARGUMENTS

4. Claims 23-29 were rejected under 35 U.S.C. 112, first paragraph, for failing to be enabled for enhancing the physiological and pathophysiological conditions mediated by androgens

comprising administration of equol. This rejection is moot in light of Applicants' amendments to Claims 23-25 and 29 and cancellation of Claims 26-28.

5. Claims 30-44 were rejected under 35 U.S.C. 112, first paragraph, for failing to be enabled for preventing an androgen-related condition comprising administration of equol. This rejection is moot in light of Applicants' amendments to Claims 30, 31, 35, and 36 and cancellation of Claims 32-34 and 37-44.

6. Claims 27, 28, 32, and 33 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite. This rejection is moot in light of Applicants' cancellation of Claims 27, 28, 32, and 33.

7. Claims 23-26, 30, 31, and 35-44 were rejected under 35 U.S.C. 102(b) as being anticipated by Kelly, et al. (International Application No. WO 98/08503, 1998, provided in IDS). Applicants traversed this rejection on the grounds that Kelly, et al., does not anticipate the amended Claims 23-25, 30, 31, 35, and 36. Specifically, the amended claims recite the limitation that equol comprising at least 1% R-equol is administered to mediate androgen hormone action so as to ameliorate at least one condition of the prostate. Applicants argue that Kelly, et al., does not specifically contemplate the stereochemistry, and that the reference in Kelly, et al., to "compound 10" could be construed to be either equol or dehydroequol. Thus, Applicants assert, Kelly, et al., does not anticipate all of the limitations of the newly amended claims. Examiner respectfully disagrees.

8. Kelly, et al., specifically contemplates equol, but not dehydroequol, for the treatment of prostate cancer (Example 6B). Furthermore, Kelly, et al., discloses the presence of a chiral center, yet does not specify the enantiomer of equol. Since the equol was produced via synthesis

(pg 28, lines 15-26), one of ordinary skill would reasonably interpret that the equol composition disclosed by Kelly, et al., was racemic, which means that 50% of the equol was R-equol, and 50% was S-equol. Thus, meeting the limitation of "at least 1% was R-equol" recited in the amended claims. In the absence of a definition of "ameliorate" in the instant specification, Examiner interprets "to ameliorate" as "to treat." Claims 23-25, 30, 31, 35, and 36 are drawn to a treatment of a condition of the prostate, which includes benign prostate hyperplasia (BPH) and prostate cancer. Kelly, et al., further teach an oral composition, wherein the daily dose is between 0.1 mg- 2.0 g (pg 9, lines 15-16), thus meeting the limitation of 1 mg equol.

9. Claims 23 and 30 contain "wherein" clauses disclosing the intended result of the method (i.e. the R-equol binding 5α-DHT). The intended result of a method is not considered to be a patentably distinguishing feature of an invention. "[A] whereby clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited.'" *Hoffer v. Microsoft Corp.*, 405 F.3d 1326, 1329, 74 USPQ2d 1481, 1483 (Fed. Cir. 2005) (MPEP § 2111.04). Therefore, the rejection of amended Claims 23-25, 30, 31, 35, and 36 is maintained. The rejection of Claims 37-44 is moot in light of Applicants' cancellation of said claims.

10. Claims 23, 24, 28, 30, 31, and 33 were rejected under 35 U.S.C. 102(b) as being anticipated by Gorbach (International Application No. WO 98/25588) as evidenced by Setchell, et al. (American Journal of Clinical Nutrition). Applicants traversed this rejection on the grounds that one of ordinary skill in the art at the time the invention was made would know that isoflavones are converted to S-equol, *in vivo*. Examiner finds this argument to be persuasive. Thus, this rejection is withdrawn.

11. Claims 23, 24, 27, 30, 31, and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Setchell and Cole (US PreGrant Publication No. 2004/0235758) Applicants traverse this rejection on the grounds that Setchell and Cole do not qualify as prior art. The 1.131 declaration signed by Dr. Edwin Lephart has been filed on 02/10/2009 to support this allegation. The 1.131 declaration by Dr. Edwin Lephart filed on 02/10/2009 under 37 CFR 1.131 has been considered but is ineffective to overcome the Setchell and Cole reference. The declaration does not include the signature of all inventors associated with invention of the rejected claims. To be effective, the declaration must include all inventors of the subject matter claimed. "An affidavit or declaration by less than all named inventors of an application is accepted where it is shown that less than all named inventors of an application invented the subject matter of the claim or claims under rejection. For example, one of two joint inventors is accepted where it is shown that one of the joint inventors is the sole inventor of the claim or claims under rejection." (MPEP § 715.04(I)(B)) The Lephart Declaration clearly states that all of the inventors of the instant application collaborated on the instant invention prior to the Setchell and Cole reference. As such, the declaration must be signed by all inventors to overcome said reference. The amendments to Claims 23, 24, 30, 31, and 32 does not overcome the rejection. Therefore, the rejection of Claims 23, 24, 30, 31, and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Setchell and Cole is maintained. The rejection of Claim 27 is moot in light of Applicants' cancellation of said claim.

12. Claims 23, 29, 30, 34, 38, 42, and 43 were rejected under 35 U.S.C. 103(a) as being unpatentable over Kelly, et al., in view of Luk, et al. (Journal of Natural Products). Applicants traversed this rejection on the grounds that neither Kelly, et al., nor Luk, et al., do not fairly teach

or suggest administration of a mixture of R- and S-equol. Examiner finds Applicants argument persuasive. Thus, the rejection of Claims 23, 29, and 30 under 35 U.S.C. 103(a) is withdrawn. The rejection of Claims 34, 38, 42, and 43 is moot in light of Applicants' cancellation of said claims.

13. Amended Claims 23-25, 29-31, 35, and 36, and newly added Claims 45 and 46 are examined on their merits and the following **FINAL** rejection is made.

Claim Rejections - 35 USC § 112 (2nd paragraph)

14. The text of Title 35, U.S.C. §112, second paragraph, not included in this action can be found in a prior Office action.

15. Claims 23-25, 29, 30, 35, 36, 45, and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejected claims recite the limitations "mediating hormone action" and/or "condition of the prostate." Neither the instant specification nor define what is meant by either term. As such, the metes and bounds of the rejected Claims are unclear and the Claims are thus considered indefinite.

Claim Rejections - 35 USC § 102

16. The text of Title 35, U.S.C. §102(b) not included in this action can be found in a prior Office action.

17. Claims 45 and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Kelly et al. (International Application No. WO 98/08503, 1998, already of record).

18. Claim 45 is drawn to a method of mediating androgen hormone action so as to ameliorate BPH comprising equol sufficient to bind free 5α-DHT to inhibit binding of the 5α-DHT with the androgen receptor. Claim 46 is drawn to a method of co-mediating androgen hormone actions and estrogen action so as to ameliorate BPH. Claims 45 and 46 contain "thereby" clauses disclosing the intended result of the method (i.e. the R-equol binding 5α-DHT). The intended result of a method is not considered to be a patentably distinguishing feature of an invention (MPEP § 2111.04).

19. Kelly, et al., teaches that administration of one of compounds 1-10 (which includes equol) or clover isoflavone to patients suffering from BPH resulted in the "significant decrease in the rate of production of relevant cancer markers" (Example 10, lines 7-15). Setchell, et al. (American Journal of Clinical Nutrition, 2005, already of record) teach that the exclusive product of isoflavones is S-equol (abstract). The isoflavone administered by Kelly, et al., necessarily and inherently were converted to S-equol prior to mediating. Therefore, Kelly, et al., anticipate all the limitations of the rejected claims.

Conclusion

20. Claims 23-25, 29-31, 35, 36, 45, and 46 are rejected.

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Zarek whose telephone number is (571) 270-5754. The examiner can normally be reached on Monday-Thursday, 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PEZ

/Rita J. Desai/
Primary Examiner, Art Unit 1625